70

Supreme Court, U.S.
FILED
OCT 18 2007
OFFICE OF THE CLERK

No. 07-521

IN THE
Supreme Court of the United States

RICHARD WARD, ET AL., PETITIONERS

v.

WASHINGTON UNIVERSITY, RESPONDENT.

Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Eighth Circuit

PETITION FOR A WRIT OF CERTIORARI

PAUL M. SMITH
Counsel of Record
ELAINE J. GOLDENBERG
MATTHEW S. HELLMAN
JENNER & BLOCK LLP
601 Thirteenth Street, NW
Washington, D.C. 20005
(202) 639-6000
Counsel for Petitioners
Richard Ward, Thomas
McGurk, Jr., Luis Garcia,
Antonio Castro, Philip
Wilard, Ivan Parron, James
D. Ellis, Mike Missios

QUESTION PRESENTED FOR REVIEW

Whether state common law preempts federal regulatory law and the specific guidance of a federal agency defining the petitioners' property rights in their own body tissue used for medical research?

LIST OF PARTIES

Pursuant to Rule 14.1(b), the following list identifies all of the parties before the United States Court of Appeals for the Eighth Circuit.

Richard N. Ward, Thomas A. McGurk, Jr., Luis Garcia, Antonio Castro, Philip Wilard, Ivan Parron, James D. Ellis, Mike Missios, and William J. Catalona were the appellants below.

Washington University was the appellee below.

TABLE OF CONTENTS

QUESTION PRESENTED FOR REVIEW i

LIST OF PARTIES ii

TABLE OF AUTHORITIES v

PETITION FOR A WRIT OF CERTIORARI 1

OPINIONS BELOW 1

JURISDICTION 1

FEDERAL REGULATORY PROVISION INVOLVED 1

INTRODUCTION 2

STATEMENT OF THE CASE 4

REASONS FOR GRANTING THE WRIT 10

I. The Ruling Of The Eighth Circuit That The University Owns Tissue And Blood Samples Provided For Use In Research Will Have A Broad Impact Nationwide 12

II. The Ruling Of The Eighth Circuit Collides With Binding Federal Regulations 16

A. The Common Rule Prohibits Transfer Of Ownership 17

B. The OHRP's Authoritative Guidance Requires Reversal Of The Eighth Circuit 21

C. The Research Participants Properly Invoked The Federal Regulations As A Constraint On State Property Law In This Context 23

CONCLUSION 25

Appendix A

Opinion, *Washington University v. Catalona*, No. 06-2286 (8th Cir. June 20, 2007)..... 1a

Appendix B

Judgment, *Washington University v. Catalona*, No. 06-2286 (8th Cir. June 20, 2007)..... 19a

Appendix C

Memorandum Opinion, *Washington University v. Catalona*, No. 4:03CV1065SNL (E.D. Mo. Mar. 31, 2006)..... 21a

Appendix D

Order, *Washington University v. Catalona*, No. 4:03CV1065SNL (E.D. Mo. Mar. 31, 2006)..... 58a

TABLE OF AUTHORITIES

CASES

Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) 16

Geier v. American Honda Motor Co., 529 U.S. 861 (2000) 16, 21, 24

Long Island Care at Home, Ltd. v. Coke, 127 S. Ct. 2339 (2007) 21, 22, 23

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) 16, 24

Planned Parenthood of Houston v. Sanchez, 403 F.3d 324 (5th Cir. 2005) 24

REGULATIONS

45 C.F.R. § 46.101 16

45 C.F.R. § 46.102 18

45 C.F.R. § 46.116 ..... 3, 6, 7, 17, 18, 21

MISCELLANEOUS

Lori Andrews, *Who Owns Your Body? A Patient's Perspective on* Washington University v. Catalona, 34 J.L. Med. & Ethics 398 (2006) 13, 15

R. Alta Charo, *Body of Research: Ownership and Use of Human Tissue*, 355 New Eng. J. Med. 1517 (2006) 13

Michael Crichton, Opinion, *Body Snatchers, 2006*, Wall St. J., Dec. 15, 2006 13-14

DNA Files: Who Owns Our DNA? (Chicago Public Radio broadcast, Oct. 10, 2007), *available at* http://www.chicagopublicradio.org/Cityroom_Story.aspx?storyID=13902 14

Michael A. Goldman, *Calamity Gene*, 445 Nature 819 (2007) 13

Guidance for Institutional Review Boards and Clinical Investigators (Question 52), *available at* http://www.fda.gov/oc/ohrt/irbs/faqs.html (last visited Oct. 16, 2007) 22

Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens in Research*, 293 J. Am. Med. Assn. 1325-26 (2005) 13

Jocelyn Kaiser, *Issues with Tissues*, 316 Science 1829 (2007) 13

Jocelyn Kaiser, *Biomedical Research: Court Decides Tissue Samples Belong to University, Not Patients*, 312 Science 346 (2006) 13

Office for Protection of Research Risks [now known as Office for Human Research Protections], *"Exculpatory Language" in Informed Consent*, *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm (last visited Oct. 16, 2007) 7, 21-22

Rebecca Skloot, *Taking the Least of You*, New York Times Mag., Apr. 16, 2006 14

U.S. Gen. Accounting Office, GAO 01-775T, *Human Subjects Research: HHS Takes Steps To Strengthen Precautions, But Concerns Remain* (May 2001) 14

Cheryl Wittenauer, *Court: University Owns Research Samples*, USA Today, June 22, 2007 13

PETITION FOR A WRIT OF CERTIORARI

Petitioners Richard Ward, *et al.*, respectfully request this Court to issue a writ of certiorari to review a decision of the United States Court of Appeals for the Eighth Circuit.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Eighth Circuit, reported at 490 F.3d 667 (8th Cir. 2007), is reprinted at Pet. App. 1a. The decision of the United States District Court for the Eastern District of Missouri, reported at 417 F. Supp.2d 985 (E.D. Mo. 2006), is reprinted at Pet. App. 21a.

JURISDICTION

The Court of Appeals' judgment was entered on June 20, 2007. This Court, per Justice Alito, granted a 30-day extension for filing a petition for certiorari on September 18, 2007. Petitioners invoke the jurisdiction of this Court pursuant to 28 U.S.C. § 1254(1).

FEDERAL REGULATORY PROVISION INVOLVED

This case involves 45 C.F.R. Part 46, known as the "Common Rule."

INTRODUCTION

This case presents questions as fundamental and important as those the Court has faced in the areas of reproductive choice and euthanasia. Dr. William Catalona, the preeminent prostate surgeon and researcher at Washington University ("the University"), oversaw research that asked thousands of men to provide tissue samples from cancerous prostate glands, while also collecting blood samples from those patients, their families, and others. These research participants (sometimes referred to hereafter as "RPs") generally lacked any independent knowledge about the risks and benefits of providing samples of their biological matter, making the decision to allow the use of their samples only after consultation with University personnel about their rights. The participants' rights were memorialized in consent forms drafted by the University. The forms varied over time but consistently provided that the research participants could end their participation at any point, bar further use of their samples, and even insist that the samples be destroyed. None of the consent forms ever stated that the University would become the owner of the RPs' tissue or blood.

When Dr. Catalona – a man whom many of the RPs credited with saving their lives – left for Northwestern University, petitioners and more than 6,000 other research participants directed Washington University to transfer the samples to Northwestern. Washington University refused and brought this action, arguing under state common law that it retained sole title to the samples.

In response, the research participants pointed to governing federal law. The U.S. Department of Health and Human Services regulates federally funded medical research, and has established the "Common Rule" to protect patient rights and ensure informed consent. That set of regulations provides that "[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject . . . is made to waive or appear to waive any of the subject's legal rights." 45 C.F.R. § 46.116. The agency's Office for Human Research Protections ("OHRP") has interpreted the rule by giving examples of consent form language that the regulations prohibit. This is one example of a prohibited provision: "By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of research."

The federal district court discounted the agency's guidance entirely, concluding that the Common Rule did nothing more than prohibit the research institution from requiring the research participant to waive the right to file a tort action for malpractice or other negligence. The U.S. Court of Appeals for the Eighth Circuit affirmed, ruling under state law that the University had acquired ownership of the samples – and doing so without devoting a word of its opinion to the federal regulations or the agency's guidance. In so ruling, the courts disregarded the fact that federal regulations governing this research, and much of the rest of the medical research in this country, *prohibit* such a transfer of ownership.

This Court should grant review because the Eighth Circuit has established a precedent with breathtaking consequences for the petitioners and the many others who have provided (or might provide) tissue and blood samples for medical research. The question of the effect of the federal regulations in this important and sensitive context should be settled by this Court.

STATEMENT OF THE CASE

Dr. Catalona worked at Washington University from 1976 to 2003. During that time, he performed thousands of prostate surgeries. He also was instrumental in the creation of an enormously valuable biorepository of prostate tissue samples, blood samples, and DNA samples stored for use in research. His research led to the development of the PSA (prostate-specific antigen) test used to detect prostate cancer.

By 2003, the biorepository contained 3,500 tissue samples obtained during prostate cancer surgeries, and tens of thousands of samples of blood and other bodily fluids. To facilitate studies of the genetic aspects of disease, all of the samples were linked to identifying information about the individuals who provided them.

The research participants allowed the use of their tissue only conditionally. Dr. Catalona and the University presented the research participants with consent forms and, in most cases, an informational brochure that explained and governed their rights. The consent forms referred to the provision of samples as a "donation," but they also made clear

that a research participant could discontinue participation or withdraw consent at any time. Pet. App. 5a-6a. The accompanying brochure, which the research participants also signed, stated explicitly that a research participant could change his mind and ask that his samples no lo ger be used in research or even be destroyed. Pet. App. 6a. And these various documents also described the risks to the patients and their families of participating in genetics research, including the risk of discrimination in insurance and employment if the results were disseminated outside the confines of the study.

Dr. Catalona moved to Northwestern Medical School in 2003 and, at his request, about 6,000 people filed authorizations addressed to the University directing it to transfer their samples to Dr. Catalona at Northwestern. These requests led the University to file suit against Dr. Catalona seeking a declaratory judgment that it was the rightful owner of all materials in the biorepository. Dr. Catalona counterclaimed seeking a judgment that the tissue samples had been entrusted by the research participants to him and that he therefore had the right to possess them and continue the research that the RPs had authorized him to undertake. He also argued that the University's ownership claim violated the governing federal regulations.

Petitioners are eight research participants whom the district court added as additional defendants in the litigation between Dr. Catalona and the University. They were treated in the courts below as

representatives of the interests of the thousands of research participants who had asked to have their samples transferred to Dr. Catalona.[1] They argued that they retain all ownership rights in the samples under state law, by virtue of the language of the consent forms, and that they therefore have the right to direct that samples be transferred to Northwestern. They also consistently argued that the consent forms could not, as the University claimed, be read as conferring ownership on the University because federal regulations bar the University from even asking for such a surrender of the research participants' ownership of materials from their own bodies.

The regulatory requirements applicable to federally funded research like that conducted at the University are set forth in 45 C.F.R. Part 46, known as the "Common Rule." Among other things, the Common Rule requires that federally funded researchers obtain informed consent from anyone who becomes involved in medical research. 45 C.F.R. § 46.116. The elements that must be included in the informed consent request include a "statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." *Id.* § 46.116(a)(8).

---

[1] Petitioners initially sought to intervene in the case. The district court denied that motion but then added petitioners as defendants, holding that they were "necessary parties" under Federal Rule of Civil Procedure 19.

Most significantly, the federal regulations do not permit forms used to obtain informed consent to "include any exculpatory language through which the subject . . . *is made to waive or appear to waive any of the subject's legal rights*, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence." *Id.* § 46.116 (emphasis added). The italicized portion of the regulation has been authoritatively interpreted by the Office of Human Research Protections ("OHRP"). That document lists examples of "exculpatory" language barred by 45 C.F.R. § 46.116. This is one example of the *prohibited* language:

> By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.

See Office for Protection of Research Risks [now known as Office for Human Research Protections], "Exculpatory Language" in Informed Consent, *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm (last visited Oct. 16, 2007).

After an evidentiary hearing, the district court held that the University owned and controlled the samples under Missouri law. Pet. App. 60a-62a. The court found that the research participants intended to make an *inter vivos* gift at the time they transferred samples to the biorepository. Pet. App. 45a-47a. It also concluded that the research participants' right to discontinue participation was

not inconsistent with the finding of a transfer of ownership, because that right meant only that a research participant could choose "not to provide any more biological materials." Pet. App. 52a.

With regard to the federal regulation barring use of "exculpatory language" waiving a subject's legal rights, the district court held that this rule only barred language by which a research participant would waive the right to bring a tort action – and thus did not bar language by which the research participant transferred ownership of samples. Pet. App. 49a. In so ruling, the court rejected entirely the notion that it had some duty, in interpreting a federal regulation, to defer to the interpretation offered in a document published by those who wrote the regulation. The court held that the OHRP document is non-binding because it is not itself contained in a regulation. Pet. App. 48a (the document "merely presents an opinion by the [OHRP] regarding exculpatory language in informed consent forms and provides examples. The examples are not found in any of the federal regulations governing the GU Biorepository."). And the court further held that its reading of the regulation should govern this case, despite the direct conflict with the interpretation provided by the administering agency. Pet. App. 48a.

Both Dr. Catalona and the research participants appealed. They argued, *inter alia*, that the district court had misunderstood the promises made to research participants about their right to discontinue participation in the research at any time. Because these promises clearly included the right to stop use

of samples previously provided and even to demand that those samples be destroyed, Dr. Catalona and the research participants argued that no gift of property rights had occurred as a matter of Missouri law.

In making this argument, the research participants also relied on federal law. They argued that any interpretation of the consent forms as effecting a transfer of ownership rights was barred by the federal regulations. *E.g.*, RP Br. at 29-33 (8th Cir. filed July 12, 2006); *see* RP Reply Br. at 20 (8th Cir. filed Sept. 21, 2006) ("[T]he Common Rule's prohibition on exculpatory language, 45 C.F.R. § 46.116, bars waiver of the RPs' ownership rights in the samples provided for research.").[2] They also argued at some length that the district court's rejection of a duty to defer to the administrative interpretation was erroneous. *See, e.g.*, RP Br. at 31-33 (citing *Glover v. Standard Federal Bank*, 283 F.3d 953, 962 (8th Cir. 2002)).

---

[2] In its brief opposing a stay, the University claimed that petitioners did not really rely on federal law in making their arguments in the lower courts. That is incorrect. While it is true that they discussed state property law in the course of claiming that ownership never transferred, they also said that any contrary ruling was barred by federal law. And while they did state that the "Common Rule . . . provides an interpretative guide in this case, rather than an independent basis for the RPs' rights," RP Reply Br. at 12 n.6, that was merely to explain that there is no "private right of action" issue here. The research participants are claiming rights under state property law, and the University's interpretation of the consent forms is preempted by federal law.

The Eighth Circuit nevertheless affirmed, holding that the ownership of the samples, under Missouri law, had transferred to the University, subject only to the retained right of the research participants to direct that their samples no longer be used or be destroyed. Pet. App. 16a-18a. On that basis, the court of appeals held that the research participants had no right to ask that their samples be transferred for use by Dr. Catalona at Northwestern. Pet. App. 18a-19a.

Remarkably, the court of appeals never even referred, in its published opinion, to the Common Rule and the argument that federal law precluded treating the consent forms as a transfer of ownership rights. It never explained how an unconditional right to control use of the tissue and to exclude others by requiring the tissue's destruction (rights protected by the federal regulations) could be reconciled with the finding that ownership of the property had been transferred completely. The court simply ignored that issue without explanation.

REASONS FOR GRANTING THE WRIT

The decision of the Eighth Circuit, if left unreviewed, will have a profound impact on medical research in this country and the relationship between researchers and those whom they ask to provide samples of tissue and blood. The federal government has erected a set of protections for research participants carefully designed to preclude just the kind of implicit transfer of title and control that the court of appeals found permissible here. The Eighth Circuit's unprecedented refusal to

recognize and enforce those limitations will be cited across the country as a justification for assertions of ownership over tissue and blood samples, which contain extraordinarily sensitive personal information, and which in this day and age have both tremendous commercial value and tremendous potential for harm to research participants. That should not be allowed to occur.

The federal regulators have left no doubt that language purporting to transfer ownership of the tissues themselves may not be included in informed consent forms for patients donating bodily tissues. A natural reading of the text of the regulation leads to that conclusion, and any potential doubt is eliminated by the agency guidance document expressly barring transfers of ownership. The district court's refusal to accord deference to that interpretation was flatly improper.

Even more improper and inexplicable was the Eighth Circuit's willingness to rule that the University had become the owner of all the samples in the biorepository without even addressing the question of whether federal law permits that result. The appellants in that court devoted a significant portion of their briefs to discussing the issue, and there was no reason for excluding the federal question from consideration. Nor should the court of appeals' ruling evade review simply because it reflects errors of omission rather than commission.

That is particularly true where, as here, the explicit and implicit rulings of the court of appeals are very likely to have a broad national impact. This

dispute has been closely watched across the country as a test case establishing the rights of research participants and research institutions with regard to "donated" tissue samples. As collections of tissue samples have come to take on not just scientific value but also commercial value, the risk of abuse has become heightened. Moreover, as biological research becomes increasingly sophisticated, the risk that the samples will be used for morally sensitive endeavors not approved by research participants, or used to reveal private information about those participants, increases as well. Indeed, the Eighth Circuit's decision that the University owns the samples, subject only to the research participants' right to withdraw them from research or have them destroyed, invites such abuse. There is now nothing to prevent the University from selling the samples to the highest bidder, regardless of the particular use that bidder intends.

At a minimum, the Court should ask for the views of the Solicitor General and/or vacate and remand summarily for a ruling on the federal issue. To allow the ruling below to stand without further review would, we respectfully submit, be unjustifiable.

I. The Ruling Of The Eighth Circuit That The University Owns Tissue And Blood Samples Provided For Use In Research Will Have A Broad Impact Nationwide.

This is a landmark case. Although nominally based on Missouri law, the Eighth Circuit's decision will be viewed as establishing the ability of medical researchers receiving federal funds to take full

ownership and control of tissue samples, subject at best to the research participants' limited rights to say that the tissue should no longer be used or should be destroyed. The case thus affects not only the 6,000 research participants who allowed the use of their tissue samples here, but also every research participant who has ever provided a sample for research and every person who may do so in the future.

That is true in part because it is evident that petitioners expressly relied on the Common Rule to prevent a finding of transferred ownership, but the courts nevertheless held that such a transfer occurred and was not barred by applicable federal regulations. Moreover, those holdings – explicit in the district court and implicit in the court of appeals – have been closely watched by universities, biotechnology companies, and researchers all over this country.[3]

---

[3] The extensive coverage of this case in scientific journals, national newspapers, and a variety of other publications documents the attention these decisions have received. *See, e.g.*, Jocelyn Kaiser, *Issues with Tissues*, 316 Science 1829 (2007); Jocelyn Kaiser, *Biomedical Research: Court Decides Tissue Samples Belong to University, Not Patients*, 312 Science 346 (2006); Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens in Research*, 293 J. Am. Med. Assn. 1325-26 (2005); R. Alta Charo, *Body of Research: Ownership and Use of Human Tissue*, 355 New Eng. J. Med. 1517 (2006); Michael A. Goldman, *Calamity Gene*, 445 Nature 819-820 (2007); Lori Andrews, *Who Owns Your Body? A Patient's Perspective on* Washington University v. Catalona, 34 J.L. Med. & Ethics 398 (2006); Cheryl Wittenauer, *Court: University Owns Research Samples*, USA Today, June 22, 2007; Michael Crichton,

What that means is that, for all practical purposes, the rule effectively enunciated in this case will be the rule that applies nationwide. And research participants will be left in the same unfortunate situation facing petitioners: they may have the right to direct that researchers stop using their tissues and destroy them, but until they do so, the research institution that now owns the samples may do whatever it pleases with them regardless of what it has previously told participants about its purposes. For example, the institution can sell them to a for-profit entity, which might in turn choose to release genetic information publicly. Or the institution can transfer them for use in a research protocol far afield from the study the research participants thought they were supporting. *See generally* U.S. Gen. Accounting Office, GAO 01-775T, *Human Subjects Research: HHS Takes Steps To Strengthen Precautions, But Concerns Remain* 2 (May 2001). These risks are very real, as demonstrated by the fact that the University here has emphasized the monetary value of the biorepository. 8th Cir. App. 2:512-13. This is one of the reasons that federal regulations prohibit a federally funded research institution from seeking or obtaining fee simple ownership over the cells excised from an identifiable person's body.

Opinion, *Body Snatchers, 2006*, Wall St. J., Dec. 15, 2006; Rebecca Skloot, *Taking the Least of You*, New York Times Mag., Apr. 16, 2006; *DNA Files: Who Owns Our DNA?* (Chicago Public Radio broadcast, Oct. 10, 2007), *available at* http://www.chicagopublicradio.org/Cityroom_Story.aspx?storyID=13902.

The University has argued that other federal regulations would bar such abuses. But it simultaneously took the position that, if it removed from its records the name and demographic details of the person who was the source of the tissue, those protections would evaporate. Br. of Appellee Washington Univ. at 30-31 (8th Cir. filed Aug. 26, 2006). At that point, the University, now the owner of the tissues, could do whatever it chose.

Thus, the only way a research participant can protect himself against abuse of his tissue samples is to ask that they be destroyed. But that presents an intractable dilemma. The only way to prevent misuse of the sample, of which research participants will have no advance warning, is to prevent use of the sample for its intended purpose – aiding research on prostate cancer – by demanding its immediate destruction. That is the outcome that the Eighth Circuit's misguided ruling will lead to in many cases.

The effects of the ruling on potential research participants will be equally profound. Individuals will be far less likely to consent in the first place if they are asked to give up all ownership and control of their own tissues, without any way of knowing how their cells, blood, and DNA will be used or whether they will be sold. *See generally* Lori Andrews, *A Patient's Perspective on* Washington University v. Catalona, 34 J.L. Med. & Ethics 398 (2006). Perhaps the University believes such a regime will aid its research, but it is far more likely to discourage participation by those – like cancer survivors Richard Ward, Thomas McGurk, Luis Garcia, Antonio Castro, Philip Wiland, Ivan Parron,

James Ellis, and Michael Missios – whose trust in research institutions make research possible in the first place.

II. The Ruling Of The Eighth Circuit Collides With Binding Federal Regulations.

The Eighth Circuit's willingness to find a transfer of ownership here was erroneous. The administrative interpretation of the applicable federal regulation cannot be disregarded. Nor can state property law trump binding federal regulations.

This Court has made clear that under the Supremacy Clause of the Constitution, state law, including common law, is preempted when it conflicts with federal regulations or federal administrative determinations. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 884-85 (2000); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005); *id.* at 454-55 (Breyer, J., concurring); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504-05 (1996) (Breyer, J., concurring). Further, the Common Rule itself states that it preempts state law except to the extent that a state's law provides "additional protections," an exception that is not relevant in this case. 45 C.F.R. § 46.101(f).

Accordingly, in order to decide whether the University had become the owner of the samples in the biorepository, the courts below had to determine whether reading such a transfer of ownership into the consent forms would violate governing federal regulations. The district court seemed to accept this obligation, but then avoided the problem by refusing

to apply the relevant regulation or to defer to the interpretation of the regulation that had been adopted and published by the regulatory agency itself. The court of appeals simply ignored the issue. That was a clear legal error – the first an error of commission, the second an error of omission.

A. The Common Rule Prohibits Transfer Of Ownership.

Federal law contains a series of provisions that protect individuals who allow their biological matter to be used for research by federally funded institutions such as the University. The requirement of informed consent is a cornerstone of these protections. The first inviolable principle of human subject research is that participation must be voluntary. Thus, "no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject" (absent certain exceptions not relevant here). 45 C.F.R. § 46.116. The requirement of informed consent ensures that in dealing with sophisticated institutions individuals make knowing choices in matters that implicate their right to self-determination.

Federal law provides additional protections by making certain rights *unwaivable* even through informed consent. After stating that informed consent is required, the Common Rule provides that:

> No informed consent, whether oral or written, may include any exculpatory language through which the subject or

> the representative *is made to waive or appear to waive any of the subject's legal rights*, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. § 46.116 (emphasis added).

The district court interpreted the regulation as barring only "exculpatory language involving releases from malpractice or other negligence." Pet. App. 49a. But that interpretation has little to recommend it. The regulation bars "exculpatory language through which the subject . . . is made to waive . . . any of the subject's legal rights, *or* releases . . . the investigator, the sponsor, the institution or its agents from liability for negligence." 45 C.F.R. § 46.116 (emphasis added). The district court read the regulation as if it included only the second clause and not the first. A reasonable interpretation must give independent meaning to both clauses.

The University also argued to the Eighth Circuit that the Common Rule tolerates transfers of ownership so long as the tissue is "de-identified." That is a flawed argument. The University's primary support for its de-identification theory is a citation to 45 C.F.R. § 46.102(f), which provides that research involves a "[h]uman subject" – and thus requires informed consent – only when the researcher "obtains [d]ata through intervention or interaction with the individual" or "[i]dentifiable private information." But the researchers here indisputably "obtain[ed] . . . identifiable private

information." The University is thus forced to argue that although it obtained the materials subject to the Common Rule's limitations, it has the unilateral right to de-identify the tissues and claim full ownership over them free of federal strictures. Yet nothing in the Common Rule even suggests that such a loophole exists – and this is not surprising given the gross intrusions on human dignity it would allow. In any case, even if the Common Rule did allow backdoor de-identification, that would not give the University ownership here: the tissues in question can never be fully de-identified because they contain the DNA of the research participants, which will always be traceable to them.

Finally, the University takes the position that the Common Rule cannot possibly mean what it plainly says, because forbidding unconditional donations of research tissue would be an undesirable policy result from the University's perspective. But the policy choices here have already been made through the Common Rule itself. Federal law does not prohibit all types of tissue transfers; for example, it is possible to completely transfer ownership of a kidney under organ donation laws. But where research is federally funded, research participants cannot give identifiable tissue unconditionally, allow it to be used for any purpose the researcher chooses, and waive all their rights. That is highly sensible. The Common Rule is cognizant of the research institution's comparative sophistication. It preserves incentives for human subject participation in medical research. And it guards against the significant risk that – because the same tissue sample can be used multiple

times – a research institution will inappropriately use the tissue in a way that the research participant objects to, such as by selling it, using it for cosmetics research, using it for research that violates the person's religious beliefs, or posting results like identifiable genetic sequences on the Internet. The public interest, embodied in the Common Rule, thus favors the research participants, not the University.

The force of the regulation is inescapable – and its effect is to prevent *any* language in the consent forms, whether or not that language is expressly labeled "exculpatory," from having the effect of depriving the research participants of their pre-existing ownership rights in their bodily tissues. But the Eighth Circuit ignored this binding regulation in reading the consent forms to waive the research participants' ownership rights under Missouri law. Even if that ruling were correct under Missouri law (and it is not for the reasons that the research participants argued to the Eighth Circuit), it is absolutely precluded by the Common Rule applicable through the Supremacy Clause.[4]

---

[4] As noted in Dr. Catalona's petition for certiorari from the Eighth Circuit's decision (filed simultaneously with this petition), the decision below also conflicts with the decisions of other courts that have found that the Common Rule's protections preempt conflicting state law. *See Catalona v. Washington University*, Petition for Certiorari filed by Petitioner William J. Catalona (citing conflicting decisions).

B. The OHRP's Authoritative Guidance Requires Reversal Of The Eighth Circuit.

If there were any question about the meaning of the federal regulation in this case (and there is not), it would be laid to rest by the authoritative guidance the OHRP has provided regarding the regulation. A court interpreting a regulation is duty-bound to give substantial deference to an interpretation of the regulation later adopted by the agency that promulgated it. Indeed, "an agency's interpretation of its own regulations is 'controlling' unless 'plainly erroneous or inconsistent with'" the language of the regulation. *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2349 (2007) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)); *see also Geier*, 529 U.S. at 883 ("The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements.").

The Office for Human Research Protections, which is the enforcement arm of HHS, has given authoritative guidance regarding the meaning of § 46.116. That guidance details waivers that are impermissible under § 46.116. One such impermissible provision is a statement substantively identical to the interpretation that the Eighth Circuit gave to the consent documents here – a statement that "[b]y consenting to participate in this research, *I give up any property rights* I may have in bodily fluids or tissue samples obtained in the course of the research." *See* Office for Protection of Research Risks [now known as Office for Human Research Protections], "Exculpatory Language" in

Informed Consent, *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm (last visited Oct. 16, 2007).[5]

The OHRP's "guidance" is not merely precatory. On January 25, 2006, the OHRP directed Louisiana State University Health Science Center Shreveport to remove this language from its informed consent agreements: "By your consent to participation in this research study, you give up your property rights that you may have in your bodily fluids, substances or tissues." Indeed, even the University's own expert conceded at the district court hearing that to the extent the research participants' consent forms purport to give up property rights, they are invalid under federal law. 8th Cir. App. 2:171.

The duty to accord deference is fully applicable to a guidance document like the one at issue here. Just last Term, this Court deferred to an interpretation of a regulation contained in an "advisory memorandum" that was issued "only to internal Department personnel and which the Department appears to have written in response to this litigation." *Long Island Care at Home*, 127 S. Ct. at 2349. The Court even said it would defer to a

---

[5] Notably, the Food and Drug Administration has interpreted the same regulatory language in the same way. The FDA has prohibited use of the term "donation" in consent forms because it impermissibly suggests that the research participant is giving up property rights in the tissue – a statement that the regulation forbids. *See* Guidance for Institutional Review Boards and Clinical Investigators (Question 52), *available at* http://www.fda.gov/oc/ohrt/irbs/faqs.html (last visited Oct. 16, 2007) (citing 21 C.F.R. § 50.20).

considered interpretation of a regulation contained in a legal brief filed by the agency. *Id.* The OHRP guidance document is much more entitled to deference than such informal expressions of an agency's viewpoint.

Despite extensive briefing on the subject, the Eighth Circuit simply ignored the OHRP's binding interpretation of controlling law when it held that under state law the University was the owner of the tissues – *i.e.*, that the research participants had through their "consent to participation . . . given up [their] property rights in the tissues." Pet. App. 29a. But the obligation to defer to a reasonable administrative interpretation does not evaporate just because a court fails to acknowledge it. The Eighth Circuit's holding thus conflicts with federal law and must be reversed.

C. The Research Participants Properly Invoked The Federal Regulations As A Constraint On State Property Law In This Context.

The University takes the position that the Common Rule on which petitioners rely is not relevant because there is no private right of action to enforce that regulation. That argument is a red herring. Petitioners did not initiate an action seeking to enforce the regulation directly, such as through injunctive relief or damages. Rather, this lawsuit was initiated by the University itself, which sought to enforce its claimed state-law property rights in the disputed tissue and blood samples. In such a context, it is not only proper but

determinative for the research participants and Dr. Catalona to argue that the University's state-law ownership claims were preempted by an applicable federal regulation, regardless of whether that regulation could have been enforced via a private right of action.

The reason is quite simple. Even if a federal regulation is not directly enforceable through an implied or express federal right of action, it still can be raised as a defense to a state-law cause of action to the extent that the regulation preempts such a cause of action. Thus, for example, in *Geier v. American Honda Motor Co.*, as well as *Medtronic, Inc. v. Lohr*, the federal preemption defenses were raised by the defendants in a state-law tort suit. There is no reason to treat this case any differently.[6] The University sued claiming to be the owner of material previously excised from petitioners' bodies. Petitioners had every right to argue that interpreting the consent forms as effecting a transfer of ownership was barred by the applicable federal law.

Petitioners also had every right to expect that the Eighth Circuit would address this question rather than ignore it. This Court should act to assure that

---

[6] Even if the research participants had brought an action directly under the Common Rule, seeking to enforce that Rule against the University's claims of property ownership, there still would not have been a private right of action issue. The Supremacy Clause provides a right of action to enforce federal law as against conflicting state law. *See Planned Parenthood of Houston v. Sanchez*, 403 F.3d 324, 331-35 (5th Cir. 2005) (analyzing *Pharmaceutical Research & Manufs. of America v. Walsh*, 538 U.S. 644 (2003)).

important rights are not lost, nationwide, as a result of the unfortunate inaction of the court of appeals.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted. In the alternative, the Court should vacate and remand summarily for a ruling on the federal issue.

Respectfully submitted,

PAUL M. SMITH
Counsel of Record
ELAINE J. GOLDENBERG
MATTHEW S. HELLMAN
JENNER & BLOCK LLP
601 13th Street, NW
Washington, D.C. 20005
(202) 639-6000
Counsel for Petitioners
Richard Ward, Thomas McGurk, Jr., Luis Garcia, Antonio Castro, Philip Wilard, Ivan Parron, James D. Ellis, Mike Missios